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34151 7590 10/21/2003

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| EXAMINER |
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WALICKA, MALGORZATA A

| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/054,295

Applicant(s)

CECH ET AL.

Examiner

Malgorzata A. Walicka

Art Unit

1652

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: copies of claims used in double patenting rejection.

Art Unit: 1652

The examiner acknowledges the application; claims 1-14 are pending and are the subject of this Office Action.

DETAILED ACTION

1. Objections

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

Claim 9 is missing the word "claim" after the words "vector of " in the first line.

2. Rejections

2.1. 35 USC, section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "human reverse transcriptase (hTERT) protein, variant, or fragment having human telomerase catalytic activity" in Claim 1 is unclear, because it is unknown

Art Unit: 1652

whether the variant should also have the telomerase activity. Claims 2-14 are included in this rejection because they do not correct the language of the base claim.

Claim 1 is also rejected because the phrase "stringent hybridization conditions" is indefinite. In the art what conditions are considered "stringent" varies widely depending on the experiment and person making the determination. Therefore, it is unclear how homologous to a sequence encoding SEQ ID NO: 1 a sequence must be to be within the scope of the claim.

2.2. *Nonstatutory Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1652

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable, respectively, over claims 3 and 4 of the U.S. Patent No. 6,261,836 B1; copy of claims enclosed. An obviousness-type double patenting is appropriate where the conflicting claims are not identical, but an examined claim is either anticipated by, or would have been obvious over the reference claim (s). See e.g. *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); *In re Boodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPO 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because any expression vector claimed in claim 1-10 of the instant application is an expression vector that contains the polynucleotide claimed in claim 3 or 4 of the patent. It would have been obvious to have the polynucleotide of claim 3 of the patent and expressed it using any expression vector. Thus, the invention claimed in claims 1-10 of the application is an obvious modification of all that is claimed in claims 3-4 of U.S. Patent No. 6,261,836 B1.

Claim 11-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of the U.S. Patent No.

Art Unit: 1652

6,261836 B1; copy of claims enclosed. An obviousness –type double patenting is appropriate where the conflicting claims are not identical, but an examined claim is either **anticipated by**, or would have been obvious over the reference claim (s). See e.g. *In re Berg*, 140 F.3d 1428, 46USPQ2d1226 (Fed.Cir. 1998); *In re Boodman*, 11F.3d 1046, 29USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPO 645 (Fed. Cir. 1985).

Claims 11-14 of the instant application are directed to host cells comprising the expression vectors of claims 1-4 of the instant application. The host cells comprise a **polynucleotide that encodes a human telomerase reverse transcriptase (hTERT) protein, variant, or fragment having human telomerase catalytic activity when complexed with a telomerase RNA, wherein the polynucleotide hybridizes under stringent conditions to a polynucleotide having a sequence complementary to SEQ ID NO: 224**. Claims 11-14 of the instant application are rejected over claim 5 of the U.S. Patent No. 6,261836 B1, because claim 5 of the patent is directed to a genus of cells comprising **recombinant polynucleotide that encodes a human telomerase reverse transcriptase (hTERT) protein, variant, or fragment having human telomerase catalytic activity when complexed with a telomerase RNA, wherein the polynucleotide hybridizes under stringent conditions to a polynucleotide having a sequence complementary to SEQ ID NO: 224** (polynucleotide of claim 3 of the patent). Claim 5 of the patent is generic and anticipates claims 11-14 of the instant application, because the polynucleotide of claim 3 of the U.S. Patent No. 6,261836 B1

Art Unit: 1652

is a species of the genus of polynucleotides comprised in expression vectors of the instant application.

In addition, claims 11-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable, over claims 1 and 2 of the U.S. Patent No. 6,475,789 B1 (copy of claims enclosed), issued Nov.5, 2002. An obviousness -type double patenting is appropriate where the conflicting claims are not identical, but an examined claim is either **anticipated by**, or would have been obvious over the reference claim (s). See e.g. *In re Berg*, 140 F.3d 1428, 46USPQ2d1226 (Fed.Cir. 1998); *In re Boodman*, 11F.3 d 1046, 29USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPO 645 (Fed. Cir. 1985).

Generic claims 11-14 of the instant application are anticipated by Claim 1 and 2 of the U.S. Patent No. 6,475,789, because the patent claims being directed to the species of the genus claimed in the application anticipate said genus. Particularly, claims 11-14 of the patent are directed to a **host cell comprising a polynucleotide that encodes a human telomerase reverse transcriptase (hTERT) protein, variant, or fragment having human telomerase catalytic activity when complexed with a telomerase RNA, wherein the polynucleotide hybridizes under stringent conditions to a polynucleotide having a sequence complementary to SEQ ID NO: 224**. Claims 1 and 2 of the patent are directed to a host cell that is a mammalian cell **that contains a recombinant polynucleotide comprising a nucleic acid sequence that encodes a human telomerase reverse transcriptase (hTERT) protein, variant,**

Art Unit: 1652

or fragment having human telomerase catalytic activity when complexed with a telomerase RNA, wherein the polynucleotide hybridizes to a DNA having a sequence complementary to SEQ ID NO:1 at 5 degree C to 25 degree C. below T.sub.m in aqueous solution at 1 M NaCl, wherein T. sub. m is the melting temperature of a complementary polynucleotide hybridized to said DNA in aqueous solution at 1M NaCl, wherein the complementary polynucleotide is exactly complementary to SEQ ID NO: 1 and is the same length as the recombinant polynucleotide; SEQ ID NO: 1 of the U.S. Patent No. 6,475,789 is SEQ ID NO: 224 of the instant application. The underlined fragments of the text indicate particular species of the polynucleotide and cells that comprise them. Claims of the patent are directed to the specific species of the genus of host cells claimed in the instant application and as such anticipate claims of the instant application.

3. Conclusion

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

Art Unit: 1652


If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

Art Unit 1652



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